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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,772	12/08/2003	Steven C. Jepson	SMMDD-5128 REI	2213
29200 7590 10/23/2008 BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			EXAMINER GRAY, PHILLIP A	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 10/23/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/730,772	Applicant(s) JEPSON ET AL.	
	Examiner Phillip Gray	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/23/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to communication of 4/23/2008. Currently claims 1-90 are pending and rejected below.

Response to Arguments

Applicant's arguments filed 4/23/2008 have been fully considered but they are not persuasive. Applicants argue that the claim language of **“the second valve portion is forced radially open by the luer tip”** is not shown in the Mayer reference. It is examiners position that when given a broad reading of the term "forced open" the Mayer reference does have a luer tip which forces open the second portion of the valve.

This is shown in figures 5, 10, 15, and 16 of the prior art Mayer. During examination, claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Prater, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969). Under this broadest reasonable reading the Luer tip (near 58) does force the valve open radially (near 26). The elements disclosed in Mayer are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-13, 15-19, 21-25, 27-45, 47-51 and 53-90 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayer (U.S. Patent Number 5,470,319). Mayer discloses a connector device (needleless injection site) for establishing a connection with a male Luer assembly, an assembly which includes a male luer tip (194) and annular flange (see 176/202 in figures 15,16,17), and a connector device comprising a housing (170) with an upper end opening (near 204) and a central first passageway (unnumbered but shown in figure 9 near 147 for example which fluid flows through and male luer is received), housing has a first constant diameter portion (top portion of housing in figure 15 for example), a constant diameter second portion larger than the first (lower portion of housing in figure 15 for example) and a third intermediate portions with a changing diameter (middle portion of housing in figure 15 for example). Mayer discloses a stretched resealable valve (28, 122, or 220 for some example), which include a first portion to seal opening and upper surface that is wipable (see figures 9 and 10), a second portion (near 84 for example) and third portion (near 139 for example), and forth and split collar collapsing member (226 for example), with an annular space between extension portion and housing (note space near 106 and 90 as example in figure 9) and second passageway (unnumbered but shown in figure 9 near

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84 for example which fluid flows through and male luer is received), and an opening (147) formed in the valve that when the luer tip is inserted said first portion and second portion elastically extend and form a seal and allow fluid to be injected into the second passageway without flowing into the annular space (see figures 10 and 15-17) and some fluid remains in the second passageway when the male luer tip is removed, and a bonding agent to attach (such as sonic bonding from the disclosure or element 52/60). Concerning claims 2-5, 10-12, 16-18, 22-25, 42-44, 48-50 the valve includes a septum with an annular skirt and annular channel formed by the skirt with a distal landing (see figures 3, 4, and 7). The elements disclosed in Mayer are fully capable of satisfying all structural, functional, spatial, and operational limitations in the claims, as currently written, and the rejection is made and proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 14, 20, 26, 46 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer. Mayer discloses the claimed invention except for a generally rectangular cross section in the proximate direction. It would have been an obvious matter of design choice to form the valve with a rectangular cross section in the proximate direction, since applicant has not disclosed that this cross section formation solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a circular cross section, and in the alternative it would be within the level of ordinary skill in the art to change the circular cross section to a rectangular cross section in order to limit the flow rate by decreasing the area of the cross section, (changing from a circle to rectangle). In cases like the present, where patentability is said to be based upon particular chosen dimensions or upon another variable recited within the claims, applicant must show that the chosen dimensions are critical. As such, the claimed dimensions appear to be an obvious matter of engineering design choice and thus, while being a difference, does not serve in any way to patentably distinguish the claimed invention from the applied prior art. *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990); *In re Kuhle*, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975). Further a change in the shape of a prior art device is a design consideration within the skill of the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767